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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Engineered Tumor Infiltrating Lymphocytes for Cancer Therapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Iovance Biotherapeutics, Inc. ("Iovance"), headquartered in San Carlos, CA**.**

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5484; E-mail: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-170-2009: Inducible Interleukin-12

1. US Provisional Patent Application 61/174,046, filed April 30, 2009 (E-170-2009-0-US-01);

2. International Patent Application PCT/US2010/031988, filed April 22, 2010 (E-170-2009-0-PCT-02);
3. Australian Patent 2010241864, issued June 5, 2014 (E-170-2009-0-AU-03);
4. Canadian Patent 2,760,446, issued January 2, 2018 (E-170-2009-0-CA-04).
5. European Patent 2424887, issued September 30, 2015 (E-170-2009-0-EP-05); and
    a. Validated in DE, FR and GB
6. United States Patent 8,556,882, issued October 15, 2013 (E-170-2009-0-US-06).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

"The use of the Licensed Patent Rights to develop, manufacture, distribute, sell, and use autologous tumor infiltrating lymphocyte (TIL) adoptive cell therapy products for the treatment of cancer. Specifically excluded from this Licensed Field of Use are adoptive cell therapy products genetically engineered to express a chimeric antigen receptor and/or T cell receptor."

E-170-2009 is primarily directed to recombinant constructs for the inducible expression of Interleukin-12 (IL-12). IL-12 has been reported to be an important immunostimulatory cytokine; however, its clinical utility has been constrained, in part, by dose-limiting toxicity following systemic administration. The subject invention potentially addresses this limitation by operatively associating a nuclear factor of activated T cells (NFAT) promoter with the coding sequence for IL-12. TIL engineered to express these constructs produce and secrete IL-12 at the site of antigen binding (*exempli gratia*, in the tumor microenvironment).

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument establishing that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 20, 2022 .

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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